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5686 '00 OCT -4 A9:49

September 21, 2000

Docket 00D-1497/Docket Mngmt
Div Mngmt Sys, Office Human Res, FDA
5630 Fishers Lane, Rm. 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

This is written in comment concerning the draft guidance issued 9/13/00, The MQSA Final Regulations #4. On p. 11 of the document, in the data table for Survey of a mammography unit, it says the physicist must perform all tests ...900.12(e)5) ... In particular I note that 900.12(e)(5)(viii) refers to the screen speed uniformity test, which this Guidance Document #4 thereby makes a required part of a mammographic unit survey. This is in direct conflict with the letter I received from FDA/Florence Houn, M.D., M.P.H. on 2/12/98 (attached), which states at the bottom of the first page that: **"the uniformity of screen speed is part of the facility survey but not of the unit"** (survey). Dr. Houn's letter indicates that screen speed uniformity testing is excludable from a unit survey; I presume this exclusion is because the screens are not considered a direct part of the mammographic unit, in distinction from all the other tests in 900.12(e)(5), which seem obviously to be an inherent part of the mammographic unit.

I believe that this conflict arises only when the physicist's *unit* survey is performed more than once per year at any facility, separately from the physicist's *facility* survey, in order to maintain the physicist's continuing experience requirement (900.12(a)(3)(iii)(B)) in situations where the number of mammographic units under the physicist's supervision is less than 3. For example, if there are only two mammographic units, then the facility can have an annual physicist survey, and each of the two units can be surveyed twice per year (one time of which is part of the facility survey), in order to satisfy the physicist continuing experience requirements. Per Dr. Houn's letter, the second physicist unit survey done each year (separately from the facility survey) need NOT include a screen speed uniformity test, whereas the unit survey conducted during the annual facility survey must include the screen speed uniformity test.

There appears to be continuing uncertainty about the definition of a unit survey, versus definition of a facility survey; in particular to what differences exist in a unit survey when performed as a part of, versus separately from, the annual facility survey.

Sincerely,

Paul H. Brown, Ph.D.
Medical Physicist,
Assoc. Prof. Diagnostic Radiology

Attachment: Letter from Dr. Houn 2/12/98

00D-1497

CP



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Sincerely,

Paul H. Brown, Ph.D.
Medical Physicist,
Assoc. Prof. Diagnostic Radiology

Food and Drug Administration
Rockville MD 20857

February 13, 1998

MQSA Facility ID:

Paul H. Brown Ph.D.
Medical Physicist
Diagnostic Radiology (L340)-Oregon Health Sciences Univ.
3181 S.W. Sam Jackson Park Rd.
Portland, OR 97201-3098

Dear Dr. Brown :

This letter is in response to your faxed inquiry on 02/11/98 asking for clarification about several areas of the medical physics survey portion of the final Mammography Quality Standards Act (MQSA) regulations.

In answer to your questions, a mammography facility survey, as described in 900.12 (e) (9), includes not only tests of the equipment by the physicist his or herself, but review of all equipment-related aspects of the quality assurance program, including those tests performed or supervised by the quality assurance technologists. The unit survey would involve only the subset of tests performed on the unit itself. The various tests performed on the mammography system are listed in 900.12 (e) (1) through (7). With some tests, the facility has some flexibility as to whether they have them performed by the physicist, by someone under direct supervision by the physicist, by the quality control technologist and reviewed by the physicist, or by another individual under the direct supervision of the quality control technologist and reviewed by the physicist. However, as 900.12 (e) (9) indicates, the annual tests of 900.12 (e) (5) and (6) and the image quality test of 900.12 (e) (2), when done as part of either the facility or unit survey must be done by the physicist or someone under their direct supervision.

Turning to your specific situation, the first thing that should be pointed out is that the continuing experience requirement is to do two facility surveys and six unit surveys in 24 months, not one year, as you thought. This can be surveys of two (2) different facilities or the same facility twice, as long as the surveys are at least 10 months apart. Similarly the same unit can be surveyed multiple times, as long as the surveys are at least 60 days apart. You wrote that your facility has two units. When you do your annual facility survey it will also include the two (2) unit surveys. The following year when you repeat your facility survey again, you will again also include the two (2) unit surveys. Thus you will have satisfied the facility requirement and have four (4) of the six (6) unit surveys towards the unit requirement. You can resurvey your two (2) units to finish meeting the requirement or, if your circumstances permit, survey two (2) units at other facilities.

Checking the uniformity of screen speed is part of the facility survey but not of the unit. Thus you need to check the uniformity of screen speed only once a year, not six (6) times as you feared.

→ n.b. conflicts with draft Guidance #4, top p. 11, Survey of Mam Unit